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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,633	10/14/2003	Michael S. Kopreski	00-1312-L	5239

7590 11/17/2008
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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/684,633

Applicant(s)

KOPRESKI, MICHAEL S.

Examiner

FRANK W. LU

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11,13,14 and 16-35 is/are pending in the application.
- 4a) Of the above claim(s) 5-10,17-28 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,11,13,14,16,29-31 and 33-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on July 28, 2008 has been entered. The claims pending in this application are claims 1, 3, 5-11, 13, 14, and 16-35 wherein claims 5-10 and 17-28 have been withdrawn due to restriction requirement and species election mailed on April 28, 2006. Since, in the reply filed on September 28, 2006, applicant has elected the species of her2/neu-directed therapy and has not elected the species of epidermal growth factor receptor-directed therapy, newly submitted claim 32 is directed to an invention that is independent or distinct from the invention originally claimed. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 32 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Election/Restrictions

2. In view of newly amended claims 1, 3, 11, 13, 14, 16, 29-31, and 33-35, restriction to one of the following inventions is required under 35 U.S.C. 121:

- IA. Claims 1 and 31, drawn to a method for detecting epidermal growth factor receptor RNA in blood plasma from a human with colorectal cancer (claim 1) and a method for detecting epidermal growth factor receptor RNA in serum from a human with colorectal cancer (claim 31), classified in class 435, subclass 91.2.
- IB. Claims 3, 11, 13, 14, 29, and 30, drawn to a method for hybridizing her-2/neu RNA from blood plasma or serum from a human with breast cancer, or cDNA

produced therefrom (claim 3), a method for evaluating a human having breast cancer for administering a her2/neu-directed therapy (claims 11 and 13), a method for monitoring response in her-2/neu RNA in blood plasma or serum from a human with breast cancer receiving a her2/neu-directed therapy (claims 14 and 16), a method for detecting her-2/neu RNA in blood plasma from a human with breast cancer (claim 29), and a method for detecting her-2/neu RNA in serum from a human with breast cancer (claim 30), classified in class 435, subclasses 91.1 and 91.2.

IC. Claims 33-35, drawn to a method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in blood plasma from a human with lung cancer (claim 33), a method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in serum from a human with lung cancer (claim 34), and a method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in pleural fluid from a human with lung cancer (claim 35), classified in class 435, subclass 91.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups IA and IB are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IA such as colorectal cancer is not required for Group IB while the search required for Group IB such as breast cancer is not required for Group IA.

Groups IA and IC are distinct and independent inventions in that they are directed to

methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IA such as colorectal cancer is not required for Group IC while the search required for Group IC such as lung cancer is not required for Group IA.

Groups IB and IC are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IB such as breast cancer is not required for Group IC while the search required for Group IC such as lung cancer is not required for Group IB.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
November 7, 2008